REMARKS/ARGUMENTS

With entry of this amendment, claims 1, 6, 8, 22, 24-26, 34 and 35 are pending in the above-identified application. Claim 31 has been canceled without prejudice. Claim 1 has been amended as set forth in detail below. Support for this amendment is identified in the following remarks. Claim 3 has been amended to make the format associated with designation of the SEQ ID NO: consistent throughout the claim set. No new matter is added. In view of the remarks and amendments set forth herein, examination and reconsideration of all pending claims is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 3, 6, 8, and 24 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that the phrase "administered locally to the subject" is not clear because it is allegedly unclear what the meets and bounds of the term "locally" are. The Examiner suggests that one could interpret the term as referring to "a clinic with respect to the subject's home," and further alleges that it would not be clear "how far 'locally' extends (e.g. what distance away from a medical facility or tumor site would be considered 'local')." Applicants respectfully traverse.

It is well-established that a claim is definite under 35 U.S.C. § 112, second paragraph, where *one of ordinary skill in the art* would understand the scope of the claim *when read in light of the specification*. *See, e.g., North Am. Vaccine, Inc. v. American Cyanamid Co.*, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993). Thus, in determining whether a claim is definite, the Examiner is required to analyze claim language, not in a vacuum, but in light of (1) the content of the specification's disclosure; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. MPEP § 2173.02. Further, all that is required is that the claim define the subject matter with a "reasonable degree of particularity and distinctness." *Id.*

In view of the above standards, the phrase "administered locally to the subject," as recited in independent claim 3, is definite. First, with respect to the knowledge in the prior art, the phrase "local administration" is a term of art well-known to the clinician as of the filing date of the instant application. The term refers to forms of administration that make an agent available to a particular area of the body of the subject, as contrasted with "systemic administration," which refers to those forms of administration that make the agent available to the body generally. *See, e.g., Stedman's Medical Dictionary* (27th ed., 2000) (defining "local" as "confined to a limited part" or "not systemic" (page 1030, copy attached); and defining "systemic" as "relating to the entire organism as distinguished from any of its individual parts" (page 1780, copy attached). Routes of administration, known and available as of the filing date, can each be categorized by the skilled artisan as *either* systemic *or* local.

Further, the content of the specification's disclosure is consistent with this knowledge in the art. For example, the specification states that "[a]dministration can be systemic or local" (page 84, line 5) and that the therapeutic agent of the invention can be administered "*locally to the area in need of treatment*" (page 85, lines 24-26). Moreover, the examples provided in the specification for how local administration may be achieved are consistent with those methods generally known and available in the art for administering a therapeutic to a particular area of the body of the subject without affecting the body generally. (*See* specification at, *e.g.*, page 85, line 27, bridging to page 86, line 2.)

In view of the above, because the person of ordinary skill in the art (*e.g.*, a clinician) administering an agent would know which forms of administration are local versus systemic, and further because the specification's disclosure is fully consistent with this knowledge in the art, the skilled artisan would know the meaning and scope of the term "administered locally" as recited in independent claim 3. The claims therefore serve the notice function required by 35 U.S.C. § 112, second paragraph. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). Further, given a particular route of administration for delivering the Nr-CAM antisense nucleic acid to a subject to inhibit tumor cell

proliferation, the skilled artisan would know whether such administration falls with the scope of the claims.

In view of the remarks set forth above, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claims 3, 6, 8, and 24 as indefinite under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 102 or, in the alternative, under 35 U.S.C. § 103

Claims 1, 22, and 31 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over, Lane *et al.* (of record). The Examiner contends that the 1.1 kb PCR product of Lane *et al.* meets all of the structural limitations of the claimed antisense nucleic acid because, *inter alia*, "the oligonucleotide is within the size range of at least 100 nucleotides and is fully complementary to SEQ ID NO:1 ...."

Without acquiescing to the rejection or reasoning of the Examiner as it relates to claim 31, but to further expedite prosecution of certain claimed subject matter, the instant rejection is obviated with respect to claim 31 in view of the cancellation of the claim. Cancellation of claim 31 is without prejudice to continued prosecution of the subject matter encompassed by claim 31 in a related copending application. With respect to claims 1 and 22, Applicants traverse in part and overcome in part as set forth hereinbelow.

It is well-established that in order for a reference to anticipate a claim under 35 U.S.C. § 102(b), the reference must expressly or inherently disclose each and every limitation recited in the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, the reference must disclose the "identical invention ... in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In the present case, claim 1 as amended recites, *inter alia*, a "pharmaceutical composition comprising a pharmaceutical carrier and an antisense nucleic acid ..." Applicants have review Lane *et al.* and respectfully note that the 1.1 kb nucleic acid

disclosed is a PCR product generated using synthetic PCR primers. Should this nucleic acid be the 1.1 kb nucleic acid referred to by the Examiner, Applicants respectfully note that the nucleic acid is only disclosed as a probe used in Northern blotting solutions. (*See* Lane *et al.* at page 457, second column, last full paragraph). It is well-known that PCR solutions and Northern blotting solutions contain components that are not physiologically compatible (*e.g.*, formamide, SDS, and high salt concentrations such as disclosed in Lane *et al.* (*see id.*)) and, therefore, are not amenable to pharmaceutical use. Accordingly, Lane *et al.* does not disclose a "pharmaceutical composition" as presently recited in the pending claims.

Further, a *prima facie* case of obviousness under 35 U.S.C. § 103(a) requires, *inter alia*, that the Examiner show the presence of all of the recited limitations in the cited art, as well as a motivation or suggestion for modifying the cited reference to achieve the invention as claimed. *See* MPEP §§ 2142, 2143.01, and 2143.03. As set forth above, the Examiner has not shown where the cited art teaches or suggests a "pharmaceutical composition." Nor has the Examiner shown a motivation or suggestion for modifying the reference. Therefore, Lane *et al.* does not render obvious claim 1 or dependent claim 22 under 35 U.S.C. § 103(a).

In view of the remarks set forth above, Applicants respectfully request the Examiner reconsider and withdraw the rejection of claims 1 and 22 as anticipated by Lane *et al.* under 35 U.S.C. § 102(b) or, in the alternative obvious over 35 U.S.C. § 103(a).

Claim Objections

Claims 25, 26, 34, and 35 stand objected to as being dependent upon a rejected base claim, but have been indicated by the Examiner as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Because independent claims 1 and 3 are believed to be allowable for the reasons set forth above, claims 25, 26, 34, and 35, each of which depends from claim 1 or 3, should also be allowable. Therefore, Applicants respectfully request the Examiner reconsider and withdraw the objection to claims 25, 26, 34, and 35.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: 27 January 2005 By: Brian W. Poor

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